Rule 3. Licensing of Radioactive Material

410 IAC 5-3-2 Scope of rule

Sec. 2. (a) 410 IAC 5-3 provides for the licensing of radioactive material. No person shall receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to 410 IAC 5-3 or as otherwise provided in 410 IAC 5-3.

(b) Provisions for the licensing of radioactive materials as set forth in 410 IAC 5-3 shall become effective on the date of an effective agreement between the U.S. Nuclear Regulatory Commission and the state for the transfer of regulatory authority under Section 274b of the Atomic Energy Act of 1954, as amended (73 Stat 689); however, NARM materials are covered by all applicable provisions of 410 IAC 5.

(c) In addition to the requirements of 410 IAC 5-3, all licensees are subject to the requirements of 410 IAC 5-1, 410 IAC 5-4 and 410 IAC 5-10. Licensees engaged in industrial radiographic operations are subject to the requirements of 410 IAC 5-5 and licensees using sealed sources in the healing arts are subject to the requirements of 410 IAC 5-7, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of 410 IAC 5-10.1

410 IAC 5-3-3 Exemption of source materials

Sec. 3. (a) Any person is exempt from 410 IAC 5-3 to the extent that such person receives, possesses, uses, owns or transfers source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution or alloy.

(b) Any person is exempt from 410 IAC 5-3 to the extent that such person receives, possesses, uses or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

(c) Any person is exempt from 410 IAC 5-3 to the extent that such person receives, possesses, uses or transfers:

(1) Any quantities of thorium contained in:

(i) incandescent gas mantles,

(ii) vacuum tubes,

(iii) welding rods,

(iv) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium,

(v) germicidal lamps, sunlamps and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium,

(vi) rare earth metals and compounds, mixtures and products containing not more than 0.25 percent by weight thorium, uranium or any combination of these, or

(vii) personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium:

(2) Source material contained in the following products:

(i) glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material,

(ii) glassware, glass enamel and glass enamel frit containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass, glass enamel or ceramic used in construction, or

(iii) piezoelectric ceramic containing not more than 2 percent by weight source material;

(3) Photographic film, negatives and prints containing uranium or thorium;

(4) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such product or part;

(5) Uranium contained in counterweights installed in aircraft, rockets, projectiles and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

(i) The counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR Part 40.

(ii) Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM", [1]/

(iii) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED",[1]/ and

(iv) This exemption shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering;

(6) Uranium used as shielding constituting part of any shipping container which is conspicuously and legibly impressed with the legend "CAUTION RADIOACTIVE SHIELDING URANIUM" and which meets the specifications for containers for radioactive material prescribed in Section 173.394 or 173.395 of 49 CFR Part 173 of U.S. Department of Transportation regulations;

(7) Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either:

(i) the shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens, or

(ii) the receipt, possession, use or transfer of thorium contained in contact lenses or in spectacles or in eyepieces in binoculars or other optical instruments;

(8) Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium; or

(9) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

(i) the thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and

(ii) the thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

(d) The exemptions in 410 IAC 5-3-3(c)(2), do not authorize the manufacture of any of the products described.

[1]/ The requirements specified in 410 IAC 5-3-3(c)(5)(ii) and (iii) need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, "CAUTION RADIOACTIVE MATERIAL URANIUM", as previously required by 410 IAC 5.

410 IAC 5-3-4 Exemption of materials other than source materials

Sec. 4. (a) Exempt Concentrations

(1) Except as provided in 410 IAC 5-3-4(a)(2), any person is exempt from this part to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Schedule A, 410 IAC 5-3-26.

(2) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 410 IAC 5-3-4(a)(1) or equivalent regulations of the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, except in accordance with a specific license issued pursuant to 410 IAC 5-3-13(a) or the general license provided in 410 IAC 5-3-24.

(b) Exempt Quantities

(1) Except as provided in 410 IAC 5-3-4(b)(3) and (4), any person is exempt from 410 IAC 5 to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Schedule B, 410 IAC 5-3-27.

(2) 410 IAC 5-3-4(b) does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution or the incorporation of radioactive material into products intended for commercial distribution.

(3) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule B, 410 IAC 5-3-27, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under 410 IAC 5-3-4(b) or equivalent regulations of the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 or by the board pursuant to 410 IAC 5-3-13(b) which license states that the radioactive material may be transferred by the licensee to persons exempt under 410 IAC 5-3-4(b) or the equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or licensing state.[2]/

(c) Exempt Items

(1) Certain items containing radioactive material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from 410 IAC 5 to the extent that he receives, possesses, uses, transfers, owns or acquires the following products:[2]/

(i) Timepieces or hands or dials containing not more than the following specified quantities of byproduct material and not exceeding the following specified radiation dose rate:

(A) 25 millicuries of tritium per timepiece,

(B) 5 millicuries of tritium per hand,

(C) 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial),

(D) 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per any other timepiece,

(E) 20 microcuries of promethium-147 per watch hand or 40 microcuries of promethium-147 per other timepiece

hand,

(F) 60 microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial),

(G) The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(aa) For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface,

(bb) For pocket watches, 0.1 millirad per hour at 1 centimeter from any surface,

(cc) For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.

(H) One microcurie of radium-226 per timepiece in timepieces acquired prior to the effective date of 410 IAC 5.

(ii) Lock illuminators containing not more than 15 millicuries of tritium or not more than 2 millicuries of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium-147 will not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber;

(iii) Precision balances containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part;

(iv) Automobile shift quadrants containing not more than 25 millicuries of tritium;

(v) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas;

(vi) Thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat;

(vii) Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of radioactive material:

(A) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

(B) 1 microcurie of cobalt-60;

(C) 5 microcuries of nickel-63;

(D) 30 microcuries of krypton-85;

(E) 5 microcuries of cesium-137;

(F) 30 microcuries of promethium-147;

And provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber;[3]/

(viii) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:

(A) Each source contains no more than one exempt quantity set forth in Schedule B, 410 IAC 5-3-27, and

(B) Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Schedule B, 410 IAC 5-3-27, provided that the sum of such fractions shall not exceed unity.

(ix) Spark gap irradiators containing not more than 1 microcurie of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons (11.4 liters) per hour.

(2) Self-Luminous Products Containing Radioactive Material.

(i) Tritium, Krypton-85 or Promethium-147. Except for persons who manufacture, process or produce self-luminous products containing tritium, krypton-85 or promethium-147, any person is exempt from 410 IAC 5 to the extent that such person receives, possesses, uses, transfers, owns or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in 410 IAC 5-3-4(c)(2) does not apply to tritium, krypton-85 or promethium-147 used in products for frivolous purposes or in toys or adornments.

(ii) Radium-226. Any person is exempt from 410 IAC 5 to the extent that such person receives, possesses, uses, transfers or owns articles containing less than 0.1 microcurie of radium-226 which were acquired prior to the effective date of 410 IAC 5.

(3) Gas and aerosol detectors containing radioactive material.

(i) Except for persons who manufacture, process or produce gas and aerosol detectors containing radioactive material,

any person is exempt from 410 IAC 5 to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission[2]/ pursuant to Section 32.26 of 10 CFR Part 32; or a licensing state pursuant to 410 IAC 5-3-13(c) which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

(ii) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an agreement state shall be considered exempt under 410 IAC 5-3-4(c)(3)(i), provided that the device is labeled in accordance with the specific license authorizing distribution of the general licensed device, and provided further that they meet the requirements of 410 IAC 5-3-13(c).

(iii) Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a licensing state shall be considered exempt under 410 IAC 5-3-4(c)(3)(i), provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of 410 IAC 5-3-13(c).

(4) Resins containing scandium-46 and designed for sand consolidation in oil wells. Any person is exempt from 410 IAC 5 to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the board or any agreement state to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium-46.

[2]/ Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

[3]/ For purposes of 410 IAC 5-3-4(c)(1)(vii) "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents.

410 IAC 5-3-5 Types of licenses

Sec. 5. Licenses for radioactive materials are of two types: general and specific.

(a) General licenses provided in 410 IAC 5-3 are effective without the filing of applications with the board or the issuance of licensing documents to the particular persons, although the filing of a certificate with the board may be required by the particular general license. The general licensee is subject to all other applicable portions of 410 IAC 5 and any limitations of the general license.

(b) Specific licenses require the submission of an application to the board and the issuance of a licensing document by the board. The licensee is subject to all applicable portions of 410 IAC 5 as well as any limitations specified in the licensing document.

410 IAC 5-3-6 General licenses for source materials

Sec. 6. (a) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial, or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

(b) Persons who receive, possess, use or transfer source material pursuant to the general license issued in 410 IAC 5-3-6(a) are exempt from the provisions of 410 IAC 5-4 and 410 IAC 5-10 of 410 IAC 5 to the extent that such receipt, possession, use or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to 410 IAC 5-3-6.

(c) A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use or transfer source material.

(d) Depleted Uranium in Industrial Products and Devices.

(1) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 410

IAC 5-3-6(d)(2), (3), (4) and (5) depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in 410 IAC 5-3-6(d)(1) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 410 IAC 5-3-13(m) or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an agreement state.

(3)(i) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1) shall file board form "W" "Registration Certificate Use of Depleted Uranium Under General License," with the board. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on board form "W" the following information and such other information as may be required by that form:

(A) Name and address of the registrant;

(B) A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 410 IAC 5-3-6(d)(1) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(C) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in 410 IAC 5-3-6(d)(3)(i)(B).

(ii) The registrant possessing or using depleted uranium under the general license established by 410 IAC 5-3-6(d)(1) shall report in writing to the board any changes in information furnished by him in board form W "Registration Certificate Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1):

(i) Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(ii) Shall not abandon such depleted uranium;

(iii) Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 410 IAC 5-3-22. In the case where the transferee receives the depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1), the transferor shall furnish the transferee a copy of 410 IAC 5 and a copy of board form "W", 410 IAC 5-3-32. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission or agreement state's rule equivalent to 410 IAC 5-3-6(d)(1), the transferor shall furnish the transferee a copy of 410 IAC 5 and a copy of board form "W" accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or agreement state under requirements substantially the same as those in 410 IAC 5;

(iv) Within 30 days of any transfer, shall report in writing to the board the name and address of the person receiving the depleted uranium pursuant to such transfer; and

(v) Shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1)is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to the depleted uranium covered by that general license.

410 IAC 5-3-7 General licenses for materials other than source materials

Sec. 7. General Licenses* Radioactive Material Other Than Source Material. (a) Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested, and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of 410 IAC 5-1-4 through 410 IAC 5-1-9, 410 IAC 5-3-4(a)(2), 410 IAC 5-3-15, 410 IAC 5-3-22, 410 IAC 5-3-23, 410 IAC 5-3-25, 410 IAC 5-4,[4]/ and 410 IAC 5-10.

*Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

[4]/ Attention is directed particularly to the provisions of 410 IAC 5-4 which relates to the labeling of containers.

(1) Static Elimination Device. Devices designed for use as static eliminators which contain, as a sealed source or sources,

radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device or a total of not more than 50 millicuries of hydrogen-3 (tritium) per device.

(2) Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device or a total of not more than 50 millicuries of hydrogen-3 (tritium) per device.

(b) Reserved

(c) Reserved

(d) Certain Measuring, Gauging or Controlling Devices.

(1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of 410 IAC 5-3-7(d)(2), (3), and (4), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage or qualitative or quantitative chemical composition or for producing light or an ionized atmosphere.

(2) The general license in 410 IAC 5-3-7(d)(1) applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the board pursuant to 410 IAC 5-3-13(d) or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state.[5]/

[5]/ Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.

(3) Any person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license in 410 IAC 5-3-7(d)(1):

(i) Shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(ii) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator if any, at no longer than six-month intervals or at such other intervals as are specified on the label; however,

(A) Devices containing only krypton need not be tested for leakage of radioactive material, and

(B) Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(iii) Shall assure that other testing, installation, servicing and removal from installation involving the radioactive material, its shielding or containment, are performed:

(A) In accordance with the instructions provided by the labels; or

(B) By a person holding an applicable specific license from the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to perform such activities;

(iv) Shall maintain records showing compliance with the requirements of 410 IAC 5-3-7(d)(3)(ii) and (iii). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by 410 IAC 5-3-7(d)(3)(ii) shall be maintained for 1 year after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the on/off mechanism and indicator required by 410 IAC 5-3-7(d)(3)(ii) shall be maintained for 1 year after the next required test of the on/off mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by 410 IAC 5-3-7(d)(3)(iii) shall be maintained for a period of 2 years from the date of the recorded event or until the device is transferred or disposed of;

(v) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on/off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the board a report containing a brief description of the event and the remedial action taken;

(vi) Shall not abandon the device containing radioactive material;

(vii) Except as provided in 410 IAC 5-3-7(d)(3)(viii), shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state whose specific license authorizes him to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the board a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

(viii) Shall transfer the device to another general licensee only:

(A) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of 410 IAC 5 and any safety documents identified in the label on the device and within 30 days of the transfer, report to the board the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the board and the transferee; or

(B) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee; and

(ix) Shall comply with the provisions of 410 IAC 5-4-22 and 410 IAC 5-4-23 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of 410 IAC 5-4 and 410 IAC 5-10.

(4) The general license in 410 IAC 5-3-7(d)(1) does not authorize the manufacture of devices containing radioactive material.

(5) The general license provided in 410 IAC 5-3-7(d)(1) is subject to the provisions of 410 IAC 5-1-4 through 410 IAC 5-1-9, 410 IAC 5-3-15, 410 IAC 5-3-22, 410 IAC 5-3-23, and 410 IAC 5-3-25.

(e) Luminous Safety Devices for Aircraft.

(1) A general license is hereby issued to own, receive, acquire, possess and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

(i) Each device contains not more than 10 curies of tritium or 300 millicuries of promethium-147; and

(ii) Each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the board or any agreement state to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in 410 IAC 5-3-7(e)(1) are exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 except that they shall comply with the provisions of 410 IAC 5-4-22 and 410 IAC 5-4-23.

(3) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

(4) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

(5) This general license is subject to the provisions of 410 IAC 5-1-4 through 410 IAC 5-1-9, 410 IAC 5-3-15, 410 IAC 5-3-22, 410 IAC 5-3-23, and 410 IAC 5-3-25.

(f) Ownership of Radioactive Material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of 410 IAC 5-3, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

(g) Calibration and Reference Sources.

(1) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions of 410 IAC 5-3-7(g)(4) and (5), americium-241 in the form of calibration or reference sources:

(i) Any person who holds a specific license issued by the board which authorizes him to receive, possess, use and transfer radioactive material; and

(ii) Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes him to receive, possess, use and transfer special nuclear material.

(2) A general license is hereby issued to own, receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of 410 IAC 5-3-7(g)(4) and (5) to any person who holds a specific license issued by the board which authorizes him to receive, possess, use and transfer radioactive material.

(3) A general license is hereby issued to own, receive, possess, use and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of 410 IAC 5-3-7(g)(4) and (5) to any person who holds a specific

license issued by the board which authorizes him to receive, possess, use and transfer radioactive material.

(4) The general licenses in 410 IAC 5-3-7(g)(1), (2), and (3) apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the board, any agreement state or licensing state pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70.

(5) The general licenses provided in 410 IAC 5-3-7(g)(1), (2) and (3) are subject to the provisions of 410 IAC 5-1-4 through 410 IAC 5-1-9, 410 IAC 5-3-15, 410 IAC 5-3-22, 410 IAC 5-3-23, and 410 IAC 5-3-25 and 410 IAC 5-4, and 410 IAC 5-10. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

(i) Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of americium-241, 5 microcuries of plutonium or 5 microcuries of radium-226 in such sources;

(ii) Shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes the following statements as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

(A) The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION RADIOACTIVE MATERIAL THIS SOURCE CONTAINS (AMERICIUM-241). (PLUTONIUM)[6]/DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or importer

[6]/ Showing only the name of the appropriate material.

(B) The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of a licensing state. Do not remove this label.

CAUTION RADIOACTIVE MATERIAL THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or importer

(iii) Shall not transfer, abandon or dispose of such source except by transfer to a person authorized by a license from the board, the U.S. Nuclear Regulatory Commission, an agreement state, or licensing state to receive the source;

(iv) Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

(v) Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

(h) Medical Diagnostic Uses[7]/[8]/

[7]/ 410 IAC 5-3-13 requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to affix a certain identifying label to the container or in the leaflet or brochure which accompanies the radiopharmaceutical.

[8]/ The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

(1) A general license is hereby issued to any physician to receive, possess, transfer or use radioactive material set forth below for the stated diagnostic uses, provided, however, that the use is in accordance with the provision of 410 IAC 5-3-7(h)(2), (3), and (4), the radioactive material is in the form of capsules, disposable syringes or other prepackaged individual doses; and the radioactive material has been manufactured in accordance with a specific license issued by the board pursuant to 410 IAC 5-3-13(g), or by the U.S. Nuclear Regulatory Commission, any agreement state or a licensing state pursuant to equivalent rules authorizing distribution to persons generally licensed pursuant to 410 IAC 5-3-7(h) or its equivalent.

(i) Chromium-51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time;

(ii) Cobalt-57 for the measurement of intestinal absorption of cyanocobalamin;

(iii) Cobalt-58 for the measurement of intestinal absorption of cyanocobalamin;

(iv) Cobalt-60 for the measurement of intestinal absorption of cyanocobalamin;

(v) Iodine-125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(vi) Iodine-131 as sodium iodide for measurement of thyroid uptake; and

(vii) Iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(2) No physician shall receive, possess, use or transfer radioactive material pursuant to the general license established by 410 IAC 5-3-7(h)(1) until he has filed board form "U," 410 IAC 5-3-30, "Certificate Medical Use of Radioactive Material Under General License" with the board and received from the board a validated copy of the board form "U," 410 IAC 5-3-30, with certification number assigned. The generally licensed physician shall furnish on board form "U," 410 IAC 5-3-30, the following information and such other information as may be required by that form:

(i) name and address of the generally licensed physician;

(ii) a statement that the generally licensed physician is a duly licensed physician (authorized to dispense drugs) in the practice of medicine in Indiana; and

(iii) a statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use radioactive material under the general license of 410 IAC 5-3-7(h) and that he is competent in the use of such instruments.

(3) A physician who receives, possesses, or uses a pharmaceutical containing radioactive material pursuant to the general license established by 410 IAC 5-3-7(h)(1) shall comply with the following:

(i) he shall not possess at any one time, pursuant to the general license in 410 IAC 5-3-7(h)(1) more than:

(A) 200 microcuries of iodine-131,

(B) 200 microcuries of iodine-125,

(C) 5 microcuries of cobalt-57,

(D) 5 microcuries of cobalt-58,

(E) 5 microcuries of cobalt-60, and

(F) 200 microcuries of chromium-51;

(ii) he shall store the pharmaceutical until administered in the original shipping container, or a container providing equivalent radiation protection;

(iii) he shall use the pharmaceutical only for the uses authorized by 410 IAC 5-3-7(h)(1);

(iv) he shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age; and

(v) he shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the board, the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

(4) The generally licensed physician possessing or using radioactive material under the general license of 410 IAC 5-3-7(h)(1) shall report in duplicate to the board, any changes in the information furnished by him in the "Certificate Medical Use of Radioactive Material Under General License," board form "U." The report shall be submitted within 30 days after the effective date of such change.

(5) Any person using radioactive material pursuant to the general license of 410 IAC 5-3-7(h)(1) is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to the radioactive material covered by the general license.

(i) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.[8]/

[8]/ The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

(1) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 410 IAC 5-3-7(i)(2), (3), (4), (5), and (6), the following radioactive materials in prepackaged units for use in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(i) Carbon-14, in units not exceeding 10 microcuries each;

(ii) Cobalt-57, in units not exceeding 10 microcuries each;

(iii) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each;

(iv) Iodine-125, in units not exceeding 10 microcuries each;

(v) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie iodine-129 and 0.005

microcurie of americium-241 each;

(vi) Iodine-131, in units not exceeding 10 microcuries each;

(vii) Iron-59, in units not exceeding 20 microcuries each;

(viii) Selenium-75, in units not exceeding 10 microcuries each;

(2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 410 IAC 5-3-7(i)(1) until he has filed board form "V," 410 IAC 5-3-31, "Certificate In Vitro Testing with Radioactive Material Under General License," with the board and received from the board a validated copy of board form "V" with certification number assigned, or until he has been authorized pursuant to 410 IAC 5-3-11(c)(3) to use radioactive material under the general license in 410 IAC 5-3-7(i). The physician, veterinarian, clinical laboratory or hospital shall furnish on board form "V" the following information and such other information as may be required by that form:

(i) name and address of the physician, veterinarian, clinical laboratory or hospital;

(ii) the location of use; and

(iii) a statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in 410 IAC 5-3-7(i)(1) and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 410 IAC 5-3-7(i)(1) shall comply with the following:

(i) the general licensee shall not possess at any one time, pursuant to the general license in 410 IAC 5-3-7(i)(1) at any one location of storage or use, a total amount of iodine-125, iodine-131, iron-59, selenium-75, and/or cobalt-57 in excess of 200 microcuries;

(ii) the general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection;

(iii) the general licensee shall use the radioactive material only for the uses authorized by 410 IAC 5-3-7(i)(1);

(iv) the general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the board, the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier;

(v) the general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in 410 IAC 5-3-7(i)(1)(viii) as required by 410 IAC 5-4-16.

(4) The general licensee shall not receive, acquire, possess or use radioactive material pursuant to 410 IAC 5-3-7(i)(1):

(i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 410 IAC 5-3-13(h), or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any agreement state or licensing state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under 410 IAC 5-3-7(i) or its equivalent; and

(ii) Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(A) This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

_____

Name of manufacturer

(B) This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a licensing state.

_____

Name of manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 410 IAC 5-3-7(i)(1) shall report in writing to the board, any changes in the information furnished by him in the "Certificate In Vitro Testing with Radioactive Material Under General License," board form "V," 410 IAC 5-3-31. The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of 410 IAC 5-3-7(i)(1) is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to radioactive material covered by that general license, except, that such persons using the Mock Iodine-125 described in 410 IAC 5-3-7(i)(1)(viii) shall comply with the provisions of 410 IAC 5-4-16, 410 IAC 5-4-22, and 410 IAC 5-4-23.

(j) Ice Detection Devices.

(1) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the board or an agreement state to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 410 IAC 5-3-7(j)(1),

(i) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of 410 IAC 5-4-16;

(ii) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

(iii) Are exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 except that such persons shall comply with the provisions of 410 IAC 5-4-16, 410 IAC 5-4-22, and 410 IAC 5-4-23.

(3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(4) This general license is subject to the provisions of 410 IAC 5-1-4 through 410 IAC 5-1-9, 410 IAC 5-3-15, 410 IAC 5-3-22, 410 IAC 5-3-23, and 410 IAC 5-3-25.

410 IAC 5-3-9 Applications for specific licenses

Authority: IC 13-1-2-9; IC 13-1-2-11; IC 16-1-3-13
Affected: IC 13-1-2

Sec. 9. (a) Applications for specific licenses shall be filed (in triplicate) on a form prescribed by the board.

(b) The board may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the board to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(d) An application for a license may include a request for a license authorizing one or more activities.

(e) In his application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the board provided such references are clear and specific.

410 IAC 5-3-10 Approval of specific licenses; environmental reports; surety for site reclamation; long-term care fund

Sec. 10. A license application will be approved if the board determines that:

(a) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with 410 IAC 5 in such a manner as to minimize danger to public health and safety or property;

(b) The applicant's proposed equipment, facilities and procedures are adequate to minimize danger to public health and safety or property;

(c) The issuance of the license will not be inimical to the health and safety of the public; and

(d) The applicant satisfies any applicable special requirements in 410 IAC 5-3-11, 410 IAC 5-3-12, 410 IAC 5-3-13.

(e) Environmental Report, Commencement of Construction. In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, source material milling, or for the conduct of any other activity which the board determines will significantly affect the quality of the environment, the board, before commencement

of construction of the plant or facility in which the activity will be conducted, shall make a determination, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such determination shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph, the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

(f) Financial Surety Arrangements for Site Reclamation.

(1) Pursuant to applicable state statutes, and as otherwise provided, financial surety arrangements for site reclamation which may consist of surety bonds, cash deposits, certificates of deposit, deposits of government securities, letters or lines of credit, or any combination of the above for the categories of licensees listed in 410 IAC 5-3-10(f)(4) shall be established to ensure the protection of the public health and safety in the event of abandonment, default, or other inability of the licensee to meet the requirements of IC 13-1-2 and 410 IAC 5.

(i) The amount of funds to be ensured by such surety arrangements shall be based on board-approved cost estimates.

(ii) Self insurance, or any arrangement which essentially constitutes self insurance, will not satisfy the surety requirement since this provides no additional assurance other than that which already exists through license requirements.

(2) The arrangements required in 410 IAC 5-3-10(f)(1) shall be established prior to issuance of the license to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility.

(3) Amendments to licenses in effect on the effective date of 410 IAC 5 may be issued providing that the required surety arrangements are established within 90 days after the effective date of 410 IAC 5-3-10(f).

(4) The following specific licensees are required to make financial surety arrangements:

(i) major processors;

(ii) waste handling licensees;

(iii) former U.S. Atomic Energy Commission or U.S. Nuclear Regulatory Commission licensed facilities;

(iv) source material milling operations; and

(v) all others except persons exempt pursuant to 410 IAC 5-3-10(f)(5).

(5) The following persons are exempt from the requirements of 410 IAC 5-3-10(f)(1):

(i) all state, local, or other government agencies, unless they are subject to 410 IAC 5-3-10(f)(4)(ii) or (iv);

(ii) persons authorized to possess no more than 1,000 times the quantity specified in Schedule B, 410 IAC 5-3-27 or combination of radioactive material listed therein as given in Schedule B, 410 IAC 5-3-27, Note 1;

(iii) persons authorized to possess hydrogen-3 contained as hydrogen gas in a sealed source; or

(iv) persons authorized to possess radioactive noble gases in sealed sources with no radioactive daughter product with half-life greater than 30 days.

(g) Long-Term Care Requirements. Pursuant to the appropriate state statutes, and as otherwise provided, a long-term care fund shall be established by the following specific licensees prior to the issuance of the license or prior to the termination of the license if the applicant chooses at the time of the licensure to provide a surety in lieu of a long-term care fund:[9]/

(1) Waste handling licensees; and

(2) Source material milling licensees.

[9]/ Long-term care funding may also be required for former U.S. Atomic Energy Commission or U.S. Nuclear Regulatory Commission licensed facilities.

410 IAC 5-3-11 Specific licenses for human, medical and industrial uses

Sec. 11. (a) Human Use of Radioactive Material in Institutions. In addition to the requirements set forth in 410 IAC 5-3-10, a specific license for human use of radioactive material in institutions will be issued if:

(1) The applicant has appointed a medical isotopes committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of radioactive material within that institution. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced, in assay of radioactive material and protection against radiation;

(2) The applicant possesses adequate facilities for the clinical care of patients;

(3) The physician designated on the application as the individual user has substantial experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients; and

(4) The application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's

staff has substantial experience in the use of a variety of radioactive materials for a variety of human uses.

(b) Licensing of Individual Physicians for Human Use of Radioactive Material.

(1) An application by an individual physician or group of physicians for a specific license for human use of radioactive material will be approved if:

(i) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(ii) The application is for use in the applicant's practice in an office outside a medical institution;

(iii) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and

(iv) The applicant has extensive experience in the proposed use, the handling and administration of radionuclides, and where applicable, the clinical management of radioactive patients.

(2) The board will not approve an application by an individual physician or group of physicians for a specific license to receive, possess, or use radioactive material on the premises of a medical institution unless:

(i) The use of radioactive material is limited to:

(A) The administration of radiopharmaceuticals for diagnostic or therapeutic purposes,

(B) The performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered,

(C) The performance of in vitro diagnostic studies, or

(D) The calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation, and diagnostic instrumentation;

(ii) The physician brings the radioactive material with him and removes the radioactive material when he departs (the institution cannot receive, possess, or store radioactive material other than the amount of material remaining in the patient); and

(iii) The medical institution does not hold a radioactive material license under 410 IAC 5-3-11(a).

(c) Specific Licenses for Certain Groups of Medical Uses of Radioactive Material.

(1) Subject to the provisions of 410 IAC 5-3-11(c)(2), (3), and (4) an application for a specific license pursuant to 410 IAC 5-3-11(a), (b) or (d) for any medical use or uses of radioactive material specified in one or more of Groups I to VI, inclusive, of Schedule C, 410 IAC 5-3-28, will be approved for all of the uses within the group or groups which include the use or uses specified in the application if:

(i) The applicant satisfies the requirements of 410 IAC 5-3-11(a), (b) and (d);

(ii) The applicant, or the physician designated in the application as the individual user, has adequate clinical experience in the types of uses included in the group or groups;

(iii) The applicant, or the physicians and all other personnel who will be involved in the preparation and use of the radioactive material, have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups;

(iv) The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the group or groups; and

(v) The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the group or groups.

(2) Any licensee or registrant who is authorized to use radioactive material pursuant to one or more groups in 410 IAC 5-3-11(c)(1) and Schedule C, 410 IAC 5-3-28, is subject to the following conditions:

(i) For Groups I, II, IV, and V, no licensee or registrant shall receive, possess or use radioactive material except as a radiopharmaceutical manufactured in the form to be administered to the patient, labeled, packaged and distributed in accordance with a specific license issued by the board pursuant to 410 IAC 5-3-13(j), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.72 of 10 CFR Part 32, or a specific license issued by an agreement state or a licensing state pursuant to equivalent regulations.

(ii) For Group III, no licensee or registrant shall receive, possess or use generators or reagent kits containing radioactive material or shall use reagent kits that do not contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except:

(A) Reagent kits not containing radioactive material that are approved by the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state for use by persons licensed pursuant to 410 IAC 5-3-11(c) and Schedule C, 410 IAC 5-3-28, or equivalent regulations; or

(B) Generators or reagent kits containing radioactive material that are manufactured, labeled, packaged and distributed in accordance with a specific license issued by the board pursuant to 410 IAC 5-3-13(k) a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.73 of 10 CFR Part 32, or a specific license issued by an agreement state or a licensing state pursuant to equivalent regulations.

(iii) For Group VI, no licensee or registrant shall receive, possess, or use radioactive material except as contained in a source or device that has been manufactured, labeled, packaged and distributed in accordance with a specific license issued by the board pursuant to 410 IAC 5-3-13(l), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.74 of 10 CFR Part 32, or a specific license issued to the manufacturer by an agreement state or a licensing state pursuant to equivalent regulations.

(iv) For Group III, any licensee or registrant who uses generators or reagent kits shall:

(A) Elute the generator, or process radioactive material with the reagent kit, in accordance with instructions approved by the U.S. Nuclear Regulatory Commission, an agreement state or licensing state and furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit;

(B) Before administration to patients, cause each elution or extraction of technetium-99m from a molybdenum-99/technetium-99m generator to be tested to determine either the total molybdenum-99 activity or the concentration of molybdenum-99. This testing shall be conducted according to written procedures and by personnel who have been specifically trained to perform the test;

(C) Prohibit the administration to patients of technetium-99m containing more than 1 microcurie of molybdenum-99 per millicurie of technetium-99m, or more than 5 microcuries of molybdenum-99 per administered dose, at the time of administration; and

(D) Maintain for 3 years for board inspection records of the molybdenum-99 test conducted on each elution from the generator.

(v) For Groups I, II, and III, any licensee using radioactive material for clinical procedures other than those specified in the product labeling (package insert) shall comply with the product labeling regarding:

(A) Chemical and physical form;

(B) Route of administration; and

(C) Dosage range.

(3) Any licensee who is licensed pursuant to 410 IAC 5-3-11 for one or more of the medical use groups in Schedule C, 410 IAC 5-3-28, also is authorized to use radioactive material under the general license in 410 IAC 5-3-7(i) for the specified in vitro uses without filing board form "V" as required by 410 IAC 5-3-7(i)(2); provided, that the licensee is subject to the other provisions of 410 IAC 5-3-7(i).

(4) Any licensee who is licensed pursuant to 410 IAC 5-3-11(c)(1) for one or more of the medical use groups in Schedule C, 410 IAC 5-3-28, also is authorized, subject to the provisions of 410 IAC 5-3-11(c)(4) and (5), to receive, possess and use for calibration and reference standards:

(i) Any radioactive material listed in Group I, Group II, or Group III of Schedule C, 410 IAC 5-3-28, with a half-life not longer than 100 days, in amounts not to exceed 15 millicuries total;

(ii) Any radioactive material listed in Group I, Group II, or Group III of Schedule C, 410 IAC 5-3-28, with half-life greater than 100 days in amounts not to exceed 200 microcuries total;

(iii) Technetium-99m in amounts not to exceed 30 millicuries; and

(iv) Any radioactive material, in amounts not to exceed 3 millicuries per source, contained in calibration or reference sources that have been manufactured, labeled, packaged and distributed in accordance with a specific license issued by the board pursuant to 410 IAC 5-3-13(l), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.74 of 10 CFR Part 32, or a specific license issued to the manufacturer by an agreement state or a licensing state pursuant to equivalent regulations.

(5)(i) Any licensee or registrant who possesses sealed sources as calibration or reference sources pursuant to 410 IAC 5-3-11(c)(4) shall cause each sealed source containing radioactive material, other than hydrogen-3, with a half-life greater than 30 days in any form other than gas to be tested for leakage and/or contamination at intervals not to exceed 6 months. In the absence of a certificate from a transferor indicating that a test has been made within 6 months prior to the transfer, the sealed sources should not be used until tested, provided, however, that no leak tests are required when:

(A) The source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material, or

(B) The sealed source is stored and is not being used; such sources shall, however, be tested for leakage prior to any use or transfer unless they have been leak tested within 6 months prior to the date of use or transfer.

(ii) The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which contamination might be expected to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the board;

(iii) If the leak test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee or registrant

shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with 410 IAC 5-3 and 410 IAC 5-4. A report shall be filed within 5 days of the test with the board describing the equipment involved, the test results, and the corrective action taken.

(6) Any licensee or registrant who possesses and uses calibration and reference sources pursuant to 410 IAC 5-3-11(c)(4)(iv) shall:

(i) Follow the radiation safety and handling instructions approved by the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state and furnished by the manufacturer on the label attached to the source, or permanent container thereof, or in the leaflet or brochure that accompanies the source, and maintain such instruction in a legible and conveniently available form; and

(ii) Conduct a quarterly physical inventory to account for all sources received and possessed. Records of the inventories shall be maintained for inspection by the board and shall include the quantities and kinds of radioactive material, location of sources, and the date of the inventory.

(d) Human Use of Sealed Sources. In addition to the requirements set forth in 410 IAC 5-3-10, a specific license for human use of sealed sources will be issued only if the applicant or, if the application is made by an institution, the individual user:

(1) Has specialized training in the diagnostic or therapeutic use of the sealed source considered, or has experience equivalent to such training, and

(2) Is a physician.

(e) Use of Sealed Sources in Industrial Radiography. In addition to the requirements set forth in 410 IAC 5-3-10, a specific license for use of sealed sources in industrial radiography will be issued if:

(1) The applicant will have an adequate program for training radiographers and radiographer's assistants and submits to the board a schedule or description of such program which specifies the:

(i) Initial training,

(ii) Periodic training,

(iii) On-the-job training,

(iv) Means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with board rules and licensing requirements, and the operating and emergency procedures of the applicant, and

(v) Means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;

(2) The applicant has established and submits to the board satisfactory written operating and emergency procedures described in 410 IAC 5-5-13;

(3) The applicant will have an internal inspection system adequate to assure that these rules, license provisions, and the applicant's operating and emergency procedures are followed by radiographers and radiographer's assistants; the inspection system shall include the performance of internal inspections at intervals not to exceed 3 months and the retention of records of such inspections for 2 years;

(4) The applicant submits to the board a description of the overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program;

(5) The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in testing sealed sources for possible leakage and contamination and submits to the board a description of such procedures including:

(i) instrumentation to be used,

(ii) method of performing tests, and

(iii) pertinent experience of the individual who will perform the test; and

(6) The licensee shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.

410 IAC 5-3-12 Specific licenses of broad scope

Sec. 12. This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of such licenses.[10]/

[10]/ Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(a) The different types of broad licenses are set forth below:

(1) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding

quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.
(2) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Schedule D, 410 IAC 5-3-29, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule D, 410 IAC 5-3-29, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Schedule D, 410 IAC 5-3-29, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.
(3) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Schedule D, 410 IAC 5-3-29, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule D, 410 IAC 5-3-29, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in Schedule D, 410 IAC 5-3-29, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.
(b) An application for a Type A specific license of broad scope will be approved if:
(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;
(2) The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and
(3) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(i) The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management and persons trained and experienced in the safe use of radioactive material;

(ii) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(iii) The establishment of appropriate administrative procedures to assure:

(A) Control of procurement and use of radioactive material;

(B) Completion of safety evaluations of proposed uses of radiactive *[sic.]* material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(C) Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 410 IAC 5-3-12(b)(3)(iii)(B) prior to use of the radioactive material.

(c) An application for a Type B specific license of broad scope will be approved if:
(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10; and
(2) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(i) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and

(ii) The establishment of appropriate administrative procedures to assure:

(A) Control of procurement and use of radioactive material,

(B) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(C) Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with 410 IAC 5-3-12(c)(2)(ii)(B) prior to use of the radioactive material.

(d) An application for a Type C specific license of broad scope will be approved if:
(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;
(2) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

(i) A college degree at the bachelor level, or equivalent training experience, in the physical or biological sciences or in engineering, and

(ii) At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of

exposure to radiation appropriate to the type and forms of radioactive material to be used; and

(3) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

(e) Specific licenses of broad scope are subject to the following conditions:

(1) Unless specifically authorized, persons licensed pursuant to 410 IAC 5-3-12 shall not:

(i) Conduct tracer studies in the environment involving direct release of radioactive material;

(ii) Receive, acquire, own, possess, use, or transfer devices containing 100,000 curies or more of radioactive material in sealed sources used for irradiation of materials;

(iii) Conduct activities for which a specific license issued by the board under 410 IAC 5-3-11, 410 IAC 5-3-13 or 410 IAC 5-3-12.5 is required; or

(iv) Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

(2) Each Type A specific license of broad scope issued under 410 IAC 5-3-12 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(3) Each Type B specific license of broad scope issued under 410 IAC 5-3-12 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(4) Each Type C specific license of broad scope issued under 410 IAC 5-3-12 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 410 IAC 5-3-12(d).

410 IAC 5-3-12.5 Specific licenses for source material milling

Sec. 12.5. In addition to the requirements set forth in 410 IAC 5-3-9, a specific license for source material milling will be issued if the applicant submits to the board a satisfactory application as described herein and meets the other conditions specified below: (a) An application for a license to receive title to, receive, possess, and use source material for milling or byproduct material as defined in 410 IAC 5-1-2 shall address the following:

(1) Description of the proposed project or action;

(2) Area/site characteristics including geology, topography, hydrology, and meteorology;

(3) Radiological and nonradiological impacts of the proposed project or action, including waterway and groundwater impacts;

(4) Environmental effects of accidents;

(5) Long-term impacts including decommissioning, decontamination, and reclamation; and

(6) Site and project alternatives.

(b) Pursuant to 410 IAC 5-3-10(e), the applicant shall not commence construction of the project until the board has weighed the environmental, economic, technical, and other benefits against the environmental costs and has concluded that the issuance of the license is appropriate.

(c) At least 1 full year prior to any major site construction, a preoperational monitoring program shall be conducted to provide complete baseline data on a milling site and its environs. Throughout the construction and operating phases of the mill, an operational monitoring program shall be conducted to measure or evaluate compliance with applicable standards and regulations; to evaluate performance of control systems and procedures; to evaluate environmental impacts of operation; and to detect potential long-term effects.

(d) Prior to issuance of the license, the applicant shall establish financial surety arrangements consistent with the requirements of 410 IAC 5-3-10(f).

(1) The amount of funds to be ensured by financial surety arrangements shall be based on board-approved cost estimates in an approved plan for decontamination and decommissioning of mill buildings and the milling site to levels which would allow unrestricted use of these areas upon decommissioning, and the reclamation of tailings and/or waste disposal areas. The licensee shall submit this plan in conjunction with an environmental report that addresses the expected environmental impacts of the milling operation, decommissioning and tailings reclamation, and that evaluates alternatives for mitigating these impacts. In establishing specific surety arrangements, the licensee's cost estimates shall take into account total costs that would be incurred if an independent contractor were hired to perform the decommissioning and reclamation work. In order to avoid unnecessary duplication and expense, the board may accept financial sureties that have been consolidated with financial surety arrangements established to meet requirements of other federal or state agencies and/or local governing bodies for such decommissioning, decontamination, reclamation, and long-term site surveillance, provided such

arrangements are considered adequate to satisfy these requirements and that portion of the surety which covers the decommissioning and reclamation of the mill, mill tailings site and associated areas, and the long-term funding charge are clearly identified. The licensee's surety mechanism will be reviewed annually by the board to assure that sufficient funds will be available for completion of the reclamation plan if the work had to be performed by an independent contractor. The amount of surety liability should be adjusted to recognize any increases or decreases resulting from inflation, changes in engineering plans, activities performed, and any other conditions affecting costs. Regardless of whether reclamation is phased through the life of the operation or takes place at the end of operations, an appropriate portion of surety liability shall be retained until final compliance with the reclamation plan is determined. This will yield a surety that is at least sufficient at all times to cover the costs of decommissioning, decontamination, and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism must be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance could be provided with a surety instrument which is written for a specified period of time (e.g., 5 years) which must be automatically renewed unless the surety agent notifies the beneficiary (the state regulatory agency) and the principal (the licensee) some reasonable time (e.g., 90 days) prior to the renewal date of their intention not to renew. In such a situation, the surety requirement still exists and the licensee would be required to submit an acceptable replacement surety within a brief period of time to allow at least 60 days for the regulatory agency to collect.

(2) The total amount of funds for reclamation or long-term surveillance and control shall be transferred to the United States if title and custody of such material and its disposal site is transferred to the United States upon termination of a license. Such funds include, but are not limited to, sums collected for long-term surveillance and control. Such funds do not, however, include monies held as surety where no default has occurred, and the reclamation or other bonded activity has been performed.

(e) The applicant shall provide procedures describing the means employed to meet the following requirements during the operational phase of any project.

(1) Milling operations shall be conducted so that all effluent releases are below the limits of 410 IAC 5-4 and are as low as is reasonably achievable.

(2) The mill operator shall conduct daily inspection of any tailings or waste retention systems. Such inspections shall be conducted by a qualified engineer or scientist. Records of such inspections shall be maintained for review by the board.

(3) The mill operator shall immediately notify the board of the following:

(i) Any failure in a tailings or waste retention system which results in a release of tailings or waste into unrestricted areas, and

(ii) Any unusual conditions or conditions not contemplated in the design of the retention system which, if not corrected, could lead to failure of the system and result in a release of tailings or waste into unrestricted areas.

(f) Continued Surveillance Requirements for Source Material Mills Having Reclaimed Residues.

(1) The final disposition of tailings or wastes at source material milling sites should be such that the need for ongoing active maintenance is not necessary to preserve isolation. As a minimum, annual site inspections shall be conducted by the government agency retaining ultimate custody of the site where tailings or wastes are stored to confirm the integrity of the stabilized tailings or waste systems and to determine the need, if any, for maintenance and/or monitoring. Results of the inspection shall be reported to the U.S. Nuclear Regulatory Commission within 60 days following each inspection. The U.S. Nuclear Regulatory Commission may require more frequent site inspections, if, on the basis of a site-specific evaluation, such a need appears necessary due to the features of a particular tailings or waste disposal system.

(2) A minimum charge of $250,000 in 1978 dollars to cover the costs of long-term surveillance shall be paid by each mill operator to the board prior to the termination of a uranium or thorium mill license. If site surveillance or control requirements at a particular site are determined, on the basis of a site-specific evaluation, to be significantly greater than those specified in 410 IAC 5-3-13(f)(1), additional funding requirements may be specified by the board. The total charge to cover the costs of long-term surveillance shall be such that, with an assumed 1 percent annual real interest rate, the collected funds will yield interest in the amount sufficient to cover the annual costs of site surveillance. The charge will be reviewed annually to recognize or adjust for inflation.

410 IAC 5-3-13 Specific licenses to manufacture, repair, or distribute products containing radioactive materials

Sec. 13. (a) Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations. (1) In addition to the requirements set forth in 410 IAC 5-3-10, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under 410 IAC 5-3-4(a)(1) will be issued if:

(i) The applicant submits a description of the product or material into which the radioactive material will be introduced,

intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and

(ii) The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Schedule A, 410 IAC 5-3-26, that reconcentration of the radioactive material in concentrations exceeding those in Schedule A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(2) Each person licensed under 410 IAC 5-3-13(a) shall file an annual report with the board which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to 410 IAC 5-3-13(a) during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

(b) Licensing the Distribution of Radioactive Material in Exempt Quantities.[10]/

(1) An application for a specific license to distribute NARM to persons exempted from 410 IAC 5 pursuant to 410 IAC 5-3-4(b) will be approved if:

(i) The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(ii) The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(iii) The applicant submits copies of prototype labels and brochures and the board approves such labels and brochures.

(2) The license issued under 410 IAC 5-3-13(b)(1) is subject to the following conditions:

(i) No more than 10 exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

(ii) Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to 410 IAC 5-3-4(b). The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

(iii) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

(A) Identifies the radionuclide and the quantity of radioactivity, and

(B) Bears the words "Radioactive Material."

(iv) In addition to the labeling information required by 410 IAC 5-3-13(b)(2)(iii), the label affixed to the immediate container, or an accompanying brochure, shall:

(A) State that the contents are exempt from licensing state requirements;

(B) Bear the words "Radioactive Material Not for Human Use Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited Exempt Quantities Should Not Be Combined;" and

(C) Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

(3) Each person licensed under 410 IAC 5-3-13(b) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under 410 IAC 5-3-4 or the equivalent regulations of a licensing state, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the board. Each report shall cover the year ending June 30, and shall be filed within thirty (30) days thereafter. If no transfers of radioactive material have been made pursuant to 410 IAC 5-3-13(b) during the reporting period, the report shall so indicate.

[10]/ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device,

commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(c) Licensing the Incorporation of Naturally-Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under 410 IAC 5-3-4(c)(3) will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32. The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie.

(d) Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under 410 IAC 5-3-7(d).

(1) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 410 IAC 5-3-7(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state will be approved if:

(i) The applicant satisfies the general requirements of 410 IAC 5-3-10;

(ii) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(A) The device can be safely operated by persons not having training in radiological protection;

(B) Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of 10 percent of the limits specified in the table in 410 IAC 5-4-2(a); and

(C) Under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15 rems
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200 rems
Other organs	50 rems; and

(iii) Each device bears a durable, legible, clearly visible label or labels approved by the board, which contain in a clearly identified and separate statement:

(A) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information;

(B) The requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(C) The information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(aa) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____[11]/, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a state with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL

_____

Name of manufacturer or distributor

(bb) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____[11]/, are subject to a general license or the equivalent, and the regulations of a licensing state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL

_____

Name of manufacturer or distributor

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the

applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the board will consider information which includes, but is not limited to:

(i) Primary containment or source capsule;

(ii) Protection of primary containment;

(iii) Method of sealing containment;

(iv) Containment construction materials;

(v) Form of contained radioactive material;

(vi) Maximum temperature withstood during prototype test;

(vii) Maximum pressure withstood during prototype tests;

(viii) Maximum quantity of contained radioactive material;

(ix) Radiotoxicity of contained radioactive material; and

(x) Operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under 410 IAC 5-3-7(d), or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and basis for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10 percent of the limits specified in the table in 410 IAC 5-4-2(a).

(4) Each person licensed under 410 IAC 5-3-13(d) to distribute devices to generally licensed persons shall:

(i) Furnish a copy of the general license contained in 410 IAC 5-3-7(d) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in 410 IAC 5-3-7(d);

(ii) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's, agreement state's or licensing state's regulation equivalent to 410 IAC 5-3-7(d), or alternatively, furnish a copy of the general license contained in 410 IAC 5-3-7(d) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the agreement state or the licensing state. If a copy of the general license in 410 IAC 5-3-7(d) is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, agreement state or licensing state under requirements substantially the same as those in 410 IAC 5-3-7(d);

(iii) Report to the board all transfers of such devices to persons for use under the general license in 410 IAC 5-3-7(d). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the board and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to the persons generally licensed under 410 IAC 5-3-7(d) during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter;

(iv) Furnish reports to other agencies:

(A) Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 31.5 of 10 CFR Part 31;

(B) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to 410 IAC 5-3-13(d) for use under a general license in that state's regulations equivalent to 410 IAC 5-3-7(d);

(C) Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the board and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is

transferred to the generally licensed person;

(D) If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission;

(E) If no transfers have been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of that agency.

(v) Keep records showing the name, address, and the point of contact for each general licensee to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in 410 IAC 5-3-7(d), or equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state. The records should show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person and compliance with the report requirements of 410 IAC 5-3-13(d)(4).

[11]/ The model, serial number, and name of manufacturer or distributor may be omitted from this label provided the information is elsewhere specified and labeling affixed to the device.

(e) Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 410 IAC 5-3-7(e) will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10, and

(2) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, and 32.101 of 10 CFR Part 32 or their equivalent.

(f) Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium, or Radium-226 for Distribution to Persons Generally Licensed Under 410 IAC 5-3-7(g). An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under 410 IAC 5-3-7(g) will be approved if:

(1) The applicant satisfies the general requirement of 410 IAC 5-3-10, and

(2) The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

(g) Manufacture and Distribution of Radioactive Material for Medical Use Under General License. In addition to requirements set forth in 410 IAC 5-3-10, a specific license authorizing the distribution of radioactive material for use by physicians under the general license in 410 IAC 5-3-7(h) will be issued if:

(1) The applicant submits evidence that the radioactive material is to be manufactured, labeled and packaged in accordance with a new drug application which the Commissioner of Food and Drugs, Food and Drug Administration, has approved, or in accordance with a license for a biologic product issued by the Secretary, U.S. Department of Health and Human Services; and

(2) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on the label affixed to the container or appears in the leaflet or brochure which accompanies the package:

(i) This radioactive drug may be received, possessed, and used only by physicians licensed (to dispense drugs) in the practice of medicine. Its receipt, possession, use, and transfer are subject to the regulations and a general license or its equivalent of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority,

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Name of manufacturer

(ii) This radioactive drug may be received, possessed, and used only by physicians licensed (to dispense drugs) in the practice of medicine. Its receipt, possession, use, and transfer are subject to the regulations and a general license or its equivalent of a licensing state.

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Name of manufacturer

(h) Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 410 IAC 5-3-7(i) will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

(i) Carbon-14 in units not exceeding 10 microcuries each;

(ii) Cobalt-57 in units not exceeding 10 microcuries each;

(iii) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each;

(iv) Iodine-125 in units not exceeding 10 microcuries each;

(v) Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcuries of americium-241 each;

(vi) Iodine-131 in units not exceeding 10 microcuries each;

(vii) Iron-59 in units not exceeding 20 microcuries each;

(viii) Selenium-75 in units not exceeding 10 microcuries each;

(3) Each prepackaged unit bears a durable, clearly visible label:

(i) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries of iodine-125, iodine-131, selenium-75, cobalt-57, or carbon-14; 50 microcuries of hydrogen-3 (tritium); 20 microcuries of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each; and

(ii) Displaying the radiation caution symbol described in 410 IAC 5-4-11(a)(1) and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals."

(4) One of the following statements, or a substantially similar statement which contains the information called for in the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(i) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

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Name of manufacturer

(ii) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only in in vitro clinical or laboratory tests not involving internal or external administration of the material or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a licensing state.

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Name of manufacturer

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source, must also contain directions to the licensee regarding the waste disposal requirements set out in 410 IAC 5-4-16.

(i) Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under 410 IAC 5-3-10 will be approved if:

(1) The applicant satisfies the general requirements of 410 IAC 5-3-10, and

(2) The criteria of Sections 32.61, 32.62, and 32.103 of 10 CFR Part 32 are met.

(j) Manufacture and Distribution of Radiopharmaceuticials *[sic.]* Containing Radioactive Material for Medical Use Under Group Licenses. An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to 410 IAC 5-3-11(c) for the uses listed in Group I, Group II, IV, or V of Schedule C, 410 IAC 5-3-28, will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(2) The applicant submits evidence that:

(i) The radiopharmaceutical containing radioactive material will be manufactured, labeled, and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

(ii) The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(3) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and

(4)(i) The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a

statement that the radiopharmaceutical is licensed by the board for distribution to persons licensed pursuant to 410 IAC 5-3-11(c) and Schedule C, 410 IAC 5-3-28, Group I, Group II, Group IV, and Group V, as appropriate, or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state.

(ii) The labels, leaflets, or brochures required by 410 IAC 5-3-13(j)(4)(i) are in addition to the labeling required by the Food and Drug Administration and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(k) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material.[12]/ An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to 410 IAC 5-3-11(c) for the uses listed in Group III of Schedule C, 410 IAC 5-3-28, will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(2) The applicant submits evidence that:

(i) The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application approved by the Food and Drug Administration or a "Notice of Claimed Investigational Exemption for a New Drug" that has been accepted by the FDA, or

(ii) The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(3) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(4) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

(5) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

(i) Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

(ii) A statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the board pursuant to 410 IAC 5-3-11(c) and Schedule C, 410 IAC 5-3-28, Group III or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state. The labels, leaflets or brochures required by 410 IAC 5-3-13(k) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

[12]/ Although the board does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the board for use by persons licensed pursuant to 410 IAC 5-3-11(c) and Group III of Schedule C, 410 IAC 5-3-28, may submit the pertinent information specified in 410 IAC 5-3-13(k).

(l) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 410 IAC 5-3-11(c) for use as a calibration or reference source or for the uses listed in Group VI of Schedule C, 410 IAC 5-3-28, will be approved if:

(1) The applicant satisfies the general requirements in 410 IAC 5-3-10;

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) The radioactive material contained, its chemical and physical form, and amount,

(ii) Details of design and construction of the source or device,

(iii) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

(iv) For devices containing radioactive material, the radiation profile of a prototype device,

(v) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

(vi) Procedures and standards for calibrating sources and devices,

(vii) Legend and methods for labeling sources and devices as to their radioactive content, and

(viii) Instruction for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label; and

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the name of source or device is licensed by the board for distribution to persons licensed pursuant to 410 IAC 5-3-11(c) and Schedule C, 410 IAC 5-3-28, Group VI or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, provided, that such labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source.

(4) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

(5) In determining the acceptable interval for test of leakage of radioactive material, the board will consider information that includes, but is not limited to:

(i) Primary containment or source capsule;

(ii) Protection of primary containment;

(iii) Method of sealing containment;

(iv) Containment construction materials;

(v) Form of contained radioactive material;

(vi) Maximum temperature withstood during prototype tests;

(vii) Maximum pressure withstood during prototype tests;

(viii) Maximum quantity of contained radioactive material;

(ix) Radiotoxicity of contained radioactive material; and

(x) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(m) Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.

(1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 410 IAC 5-3-6(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state will be approved if:

(i) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(ii) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of 10 percent of the limits specified in 410 IAC 5-4-2(a); and

(iii) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the board will approve an application for a specific license under 410 IAC 5-3-13(m) only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The board may deny any application for a specific license under 410 IAC 5-3-13(m) if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to 410 IAC 5-3-13(m)(1) shall:

(i) Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(ii) Label or mark each unit to:

(A) Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(B) State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an agreement state;

(iii) Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

(iv)(A) Furnish a copy of the general license contained in 410 IAC 5-3-6(d) and a copy of board form "W," 410 IAC 5-3-32, to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in 410 IAC 5-3-6(d); or

(B) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or agreement state's regulation equivalent to 410 IAC 5-3-6(d) and a copy of the U.S. Nuclear Regulatory Commission's or agreement state's certificate; or alternatively, furnish a copy of the general license contained in 410 IAC 5-3-6(d) and a copy of board form "W," 410 IAC 5-3-32, to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an agreement state, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an agreement state under requirements substantially the same as those in 410 IAC 5-3-6(d).

(v) Report to the board all transfers of industrial products or devices to persons for use under the general license in 410 IAC 5-3-6(d). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the board and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under 410 IAC 5-3-6(d) during the reporting period, the report shall so indicate;

(vi)(A) Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40.

(B) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to 410 IAC 5-3-13(m) for use under a general license in that state's regulations equivalent to 410 IAC 5-3-6(d).

(C) Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person.

(D) If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

(E) If no transfers have been made to general licensees within a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state agency upon the request of that agency.

(vii) Keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 410 IAC 5-3-6(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state. The records shall be maintained for a period of 2 years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

410 IAC 5-3-14 Issuance of specific licenses; incorporation of additional requirements

Sec. 14. (a) Upon a determination that an application meets the requirements of IC 13-1-2 and 410 IAC 5, the board will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(b) The board may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to 410 IAC 5-3-14 as it deems appropriate or necessary in order to:

(1) Minimize danger to public health and safety or property;

(2) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) Prevent loss or theft of material subject to 410 IAC 5-3.

410 IAC 5-3-15 Terms and conditions of licenses; transfer

Sec. 15. (a) Each license issued pursuant to 410 IAC 5-3 shall be subject to all the provisions of IC 13-1-2, now or hereafter

in effect, and to all rules, regulations, and orders of the board.

(b) No license issued or granted under 410 IAC 5-3 and no right to possess or utilize radioactive material granted by any license issued pursuant to 410 IAC 5-3 shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the board shall, after securing full information find that the transfer is in accordance with the provisions of IC 13-1-2, and shall give its consent in writing.

(c) Each person licensed by the board pursuant to 410 IAC 5-3 shall confine his use and possession of the material licensed to the locations and purposes authorized in the license.

410 IAC 5-3-16 Expiration of licenses

Sec. 16. Except as provided in 410 IAC 5-3-17(b), each specific license shall expire at the end of the specified day in the month and year stated therein.

410 IAC 5-3-17 Renewal of licenses

Sec. 17. (a) Applications for renewal of specific licenses shall be filed in accordance with 410 IAC 5-3-9.

(b) In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the board.

410 IAC 5-3-18 Amendment of licenses

Sec. 18. Applications for amendment of a license shall be filed in accordance with 410 IAC 5-3-9 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

410 IAC 5-3-19 Criteria for renewal or amendment of licenses

Sec. 19. In considering an application by a licensee to renew or amend his license, the board will apply the criteria set forth in 410 IAC 5-3-10, 410 IAC 5-3-11, 410 IAC 5-3-12, or 410 IAC 5-3-13, as applicable.

410 IAC 5-3-20 United States nuclear regulatory commission license; expiration

Sec. 20. Persons Possessing a License for Source, Byproduct or Special Nuclear Material in Quantities Not Sufficient to Form A Critical Mass on Effective Date of 410 IAC 5. Any person who, on the effective date of 410 IAC 5, possesses a general or specific license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass, issued by the U.S. Nuclear Regulatory Commission, shall be deemed to possess a like license issued under 410 IAC 5-3 and IC 13-1-2, such license to expire either 90 days after receipt from the board of a notice of expiration of such license, or on the date of expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier.

410 IAC 5-3-21 Naturally-occurring and accelerator-produced radioactive material; expiration of license

Sec. 21. Persons Possessing Naturally-Occurring and Accelerator-Produced Radioactive Material (NARM) on Effective Date of 410 IAC 5. Any person who, on the effective date of 410 IAC 5, possesses NARM for which a specific license is required by IC 13-1-2 or 410 IAC 5-3 shall be deemed to possess such a license issued under IC 13-1-2 and 410 IAC 5-3. Such license shall expire 90 days after the effective date of 410 IAC 5; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the board.

410 IAC 5-3-22 Transfer of material

Sec. 22. (a) No licensee shall transfer radioactive material except as authorized pursuant to 410 IAC 5-3-22(c).

(b) Except as otherwise provided in his license and subject to the provisions of 410 IAC 5-3-22(c) and (d), any licensee may transfer radioactive material:

(1) To the board;[13]/

(2) To the U.S. Department of Energy;

(3) To any person exempt from 410 IAC 5-3 to the extent permitted under such exemption;

(4) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the board, the U.S. Nuclear Regulatory Commission, any agreement state or any licensing state or to any person otherwise authorized to receive such material by the federal government or any agency thereof, the board, an agreement state or a licensing state; or

(5) As otherwise authorized by the board in writing.

[13]/ A licensee may transfer material to the board only after receiving prior approval from the board.

(c) Before transferring radioactive material to a specific licensee of the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, or to a general licensee who is required to register with the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's *[sic.]* license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(d) Any of the following methods for the verification required by 410 IAC 5-3-22(c) is acceptable:

(1) The transferor may possess and read a current copy of the transferee's specific license or registration certificate;

(2) The transferor may possess a written certification that the transferee is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

(3) For emergency shipments the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date; provided, that the oral certification is confirmed in writing within 10 days;

(4) The transferor may obtain other information compiled by a reporting service from official records of the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state regarding the identity of licensees and the scope and expiration dates of licenses and registration; or

(5) When none of the methods of verification described in 410 IAC 5-3-22(d)(1) to (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the board, the U.S. Nuclear Regulatory Commission, or an agreement state or a licensing state that the transferee is licensed to receive the radioactive material.

(e) Shipment and transport of radioactive material shall be in accordance with the provisions of 410 IAC 5-3-25.

410 IAC 5-3-23 Modification of license terms and condition; suspension or revocation of license

Sec. 23. (a) The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to IC 13-1-2, or by reason of rules, regulations, and orders issued by the board.

(b) Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of IC 13-1-2, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the board to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of IC 13-1-2, or of the license, or of any rule, regulation, or order of the board.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefore, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(d) The board may terminate a specific license upon request submitted by the licensee to the board in writing.

410 IAC 5-3-24 Reciprocal licensure

Authority: IC 13-1-2-9; IC 13-1-2-11; IC 16-1-3-13
Affected: IC 13-1-2

Sec. 24. (a) Licenses of Byproduct, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

(1) Subject to 410 IAC 5, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or any agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in any calendar year provided that:

(i) The licensing document does not limit the activity authorized by such document to specified installations or locations;

(ii) The out-of-state licensee notifies the board in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be

accompanied by a copy of the pertinent licensing document. If, for a specific case, the *[sic.]* day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the board, obtain permission to proceed sooner. The board may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in 410 IAC 5-3-24(a)(1);

(iii) The out-of-state licensee complies with all applicable rules of the board and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the board;

(iv) The out-of-state licensee supplies such other information as the board may request; and

(v) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in 410 IAC 5-3-24(a)(1) except by transfer to a person:

(A) Specifically licensed by the board or by the U.S. Nuclear Regulatory Commission to receive such material, or

(B) Exempt from the requirements for a license for such material under 410 IAC 5-3-4(a).

(2) Notwithstanding the provisions of 410 IAC 5-3-24(a)(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 410 IAC 5-3-7(d)(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in Indiana provided that:

(i) Such person shall file a report with the board within 30 days after the end of each calendar quarter in which any device is transferred to or installed in Indiana. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(ii) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an agreement state;

(iii) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

(iv) The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in 410 IAC 5-3-7(d).

(3) The board may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an agreement state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(b) Licenses of Naturally-Occurring and Accelerator-Produced Radioactive Material.

(1) Subject to 410 IAC 5, any person who holds a specific license from a licensing state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within Indiana for a period not in excess of 180 days in any calendar year provided that:

(i) The licensing document does not limit the activity authorized by such document to specified installations or locations;

(ii) The out-of-state licensee notifies the board in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3 day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the board, obtain permission to proceed sooner. The board may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in 410 IAC 5-3-24(b)(1);

(iii) The out-of-state licensee complies with all applicable rules of the board and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the board;

(iv) The out-of-state licensee supplies such other information as the board may request; and

(v) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in 410 IAC 5-3-24(b)(1) except by transfer to a person:

(A) Specifically licensed by the board or by another licensing state to receive such material, or

(B) Exempt from the requirements for a license for such material under 410 IAC 5-3-4.

(2) Notwithstanding the provisions of 410 IAC 5-3-24(b)(1), any person who holds a specific license issued by a licensing state authorizing the holder to manufacture, transfer, install, or service a device described in 410 IAC 5-3-7(d)(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in Indiana provided that:

(i) Such person shall file a report with the board within 30 days after the end of each calendar quarter in which any device is transferred to or installed in Indiana. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(ii) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by a licensing state;

(iii) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

(iv) The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in 410 IAC 5-3-7(d).

(3) The board may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by a licensing state or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

410 IAC 5-3-25 Transportation of radioactive materials

Sec. 25. No person shall deliver radioactive material to a carrier for transport or transport radioactive material except as authorized in a general or specific license issued by the board or as exempted in 410 IAC 5-3-25.1.

410 IAC 5-3-25.1 Exemption of transporters

Authority: IC 13-1-2-9; IC 13-1-2-11; IC 16-1-3-13
Affected: IC 13-1-2

Sec. 25.1. (a) Common, contract and private carriers, freight forwarders, and warehousemen who are subject to the requirements of the U.S. Department of Transportation in 49 CFR 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), Section 124.3 incorporated by reference, 39 CFR 111.11 (1974), are exempt from 410 IAC 5 to the extent that they transport or store radioactive material in the regular course of their carriage for another or storage incident thereto. Common, contract and private carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to 410 IAC 5-3-25 and other applicable sections of 410 IAC 5.

(b) Any licensee is exempt from 410 IAC 5-3-25 to the extent that he delivers to a carrier for transport packages each of which contains radioactive material having a specific activity less than, or equal to, 0.002 microcurie per gram.

(c) Any licensee who delivers radioactive material to a carrier for transport, where such transport is subject to the regulations of the U.S. Postal Service, is exempt from the provisions of 410 IAC 5-3-25.

410 IAC 5-3-25.2 General licenses for carriers

Authority: IC 13-1-2-9; IC 13-1-2-11; IC 16-1-3-13
Affected: IC 13-1-2

Sec. 25.2. (a) A general license is hereby issued to any common or contract carrier not exempt under 410 IAC 5-3-25.1 to receive, possess, transport, and store radioactive material in the regular course of their carriage for another or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[14]/

(b) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[14]/

[14]/ Any notification of incidents referred to in those U.S. Department of Transportation requirements shall be filed with, or made to, the board.

(c) Persons who transport radioactive material pursuant to the general licenses in 410 IAC 5-3-25.2(a) or (b) are exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 to the extent that they transport radioactive material.

410 IAC 5-3-25.3 General licenses for delivery of materials to carriers

Authority: IC 13-1-2-9; IC 13-1-2-11; IC 16-1-3-13
Affected: IC 13-1-2

Sec. 25.3. A general license is hereby issued to deliver radioactive material to a carrier[15]/ for transport provided that:

(a) The licensee complies with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the packaging of radioactive material, and to the monitoring, marking, and labeling of those packages;

(b) The licensee has established procedures for safely opening and closing packages in which radioactive material is transported and to assure that, prior to the delivery to a carrier for transport, each package is properly closed for transport; and

(c) Prior to delivery of a package to a carrier for transport, the licensee shall assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

[15]/ For the purpose of 410 IAC 5, a licensee who transports his own licensed material as a private carrier is considered to have delivered such material to a carrier for transport.

410 IAC 5-3-25.4 Advance notice of transport of nuclear waste

Authority: IC 13-1-2-9; IC 13-1-2-11; IC 16-1-3-13
Affected: IC 13-1-2

Sec. 25.4. (a) Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport to the governor, or governor's designee,[16]/ of each state through which the waste will be transported. For the purpose of 410 IAC 5-3-25.4 "nuclear waste" means any large quantity of source, byproduct, or special nuclear material required to be in Type B packaging while transported to, through, or across state boundaries to a disposal site, or to a collection point for transport to a disposal site.

[16]/ A list of the mailing addresses of the governors and governor's designees is available upon request from the Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(b) Each advance notification required by 410 IAC 5-3-25.4 shall contain the following information:

(1) the name, address, and telephone number of the shipper, carrier, and receiver of the shipment;

(2) a description of the nuclear waste contained in the shipment as required by the regulations of the U.S. Department of Transportation, 49 CFR 172.202 and 172.203(d);

(3) the point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur;

(4) the 7-day period during which arrival of the shipment at state boundaries is estimated to occur;

(5) the destination of the shipment, and the 7-day period during which arrival of the shipment is estimated to occur; and

(6) a point of contact with a telephone number for current shipment information.

(c) The notification required by 410 IAC 5-3-25.4 shall be made in writing to the office of each appropriate governor or governor's designee and to the board. A notification delivered by mail must be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach the office of the governor, or governor's designee, at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for 1 year.

(d) The licensee shall notify each appropriate governor, or governor's designee, and the board of any changes to schedule information provided pursuant to 410 IAC 5-3-25.4. Such notification shall be by telephone to a responsible individual in the office of the governor, or governor's designee, of the appropriate state or states. The licensee shall maintain for 1 year a record of the name of the individual contacted.

(e) Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice to the governor, or governor's designee, of each appropriate state and to the board. A copy of this notice shall be retained by the licensee for 1 year.

410 IAC 5-3-26 Schedule of exempt concentrations

Authority: IC 13-1-2-9; IC 13-1-2-11; IC 16-1-3-13
Affected: IC 13-1-2

Sec. 26.

SCHEDULE A
EXEMPT CONCENTRATIONS

		Column I	Column II
Element		Gas	Liquid and
(atomic		concentration	solid concentration
number)	Isotope	ì Ci/ml[1/]	ì Ci/ml[2/]

Antimony (51)	Sb-122		$3x10^{-4}$
	Sb-124		$2x10^{-4}$
	Sb-125		$1x10^{-3}$
Argon (18)	Ar-37	$1x10^{-3}$	
	Ar-41	$4x10^{-7}$	
Arsenic (33)	As-73		$5x10^{-3}$
	As-74		$5x10^{-4}$
	As-76		$2x10^{-4}$
	As-77		$8x10^{-4}$
Barium (56)	Ba-131		$2x10^{-3}$
	Ba-140		$3x10^{-4}$
Beryllium (4)	Be-7		$2x10^{-2}$
Bismuth (83)	Bi-206		$4x10^{-4}$
Bromine (35)	Br-82	$4x10^{-7}$	$3x10^{-3}$
Cadmium (48)	Cd-109		$2x10^{-3}$
	Cd-115m		$3x10^{-4}$
	Cd-115		$3x10^{-4}$
Calcium (20)	Ca-45		$9x10^{-5}$
	Ca-47		$5x10^{-4}$
Carbon (6)	C-14	$1x10^{-6}$	$8x10^{-3}$
Cerium (58)	Ce-141		$9x10^{-4}$
	Ce-143		$4x10^{-4}$
	Ce-144		$1x10^{-4}$
Cesium (55)	Cs-131		$2x10^{-2}$
	Cs-134m		$6x10^{-2}$
	Cs-134		$9x10^{-5}$
Chlorine (17)	Cl-38	$9x10^{-7}$	$4x10^{-3}$
Chromium (24)	Cr-51		$2x10^{-2}$
Cobalt (27)	Co-57		$5x10^{-3}$
	Co-58		$1x10^{-3}$
	Co-60		$5x10^{-4}$
Copper (29)	Cu-64		$3x10^{-3}$
Dysprosium (66)	Dy-165		$4x10^{-3}$
	Dy-166		$4x10^{-4}$
Erbium (68)	Er-169		$9x10^{-4}$
	Er-171		$1x10^{-3}$
Europium (63)	Eu-152		$6x10^{-4}$
	(T_r=9.2 h)		
	Eu-155		$2x10^{-3}$
Fluorine (9)	F-18	$2x10^{-6}$	$8x10^{-3}$
Gadolinium (64)	Gd-153		$2x10^{-3}$
	Gd-159		$8x10^{-4}$
Gallium (31)	Ga-72		$4x10^{-4}$
Germanium (32)	Ge-71		$2x10^{-2}$
Gold (79)	Au-196		$2x10^{-3}$
	Au-198		$5x10^{-4}$
	Au-199		$2x10^{-3}$
Hafnium (72)	Hf-181		$7x10^{-4}$
Hydrogen (1)	H-3	$5x10^{-6}$	$3x10^{-2}$
Indium (49)	In-113m		$1x10^{-2}$
	In-114m		$2x10^{-4}$
Iodine (53)	I-126	$3x10^{-9}$	$2x10^{-5}$
	I-131	$3x10^{-9}$	$2x10^{-5}$
	I-132	$8x10^{-8}$	$6x10^{-4}$
	I-133	$1x10^{-8}$	$7x10^{-5}$
	I-134	$2x10^{-7}$	$1x10^{-3}$
Iridium (77)	Ir-190		$2x10^{-3}$
	Ir-192		$4x10^{-4}$
	Ir-194		$3x10^{-4}$
Iron (26)	Fe-55		$8x10^{-3}$
	Fe-59		$6x10^{-4}$
Krypton (36)	Kr-85m	$1x10^{-6}$	

	Kr-85	$3x10^{-6}$	
Lanthanum (57)	La-140		$2x10^{-4}$
Lead (82)	Pb-203		$4x10^{-3}$
Lutetium (71)	Lu-177		$1x10^{-3}$
Manganese (25)	Mn-52		$3x10^{-4}$
	Mn-54		$1x10^{-3}$
	Mn-56		$1x10^{-3}$
Mercury (80)	Hg-197m		$2x10^{-3}$
	Hg-197		$3x10^{-3}$
	Hg-203		$2x10^{-4}$
Molybdenum (42)	Mo-99		$2x10^{-3}$
Neodymium (60)	Nd-147		$6x10^{-4}$
	Nd-149		$3x10^{-3}$
Nickel (28)	Ni-65		$1x10^{-3}$
Niobium	Nb-95		$1x10^{-3}$
(Columbium) (41)	Nb-97		$9x10^{-3}$
Osmium (76)	Os-185		$7x10^{-4}$
	Os-191m		$3x10^{-2}$
	Os-191		$2x10^{-3}$
	Os-193		$6x10^{-4}$
Palladium (46)	Pd-103		$3x10^{-3}$
	Pd-109		$9x10^{-4}$
Phosphorus (15)	P-32		$2x10^{-4}$
Platinum (78)	Pt-191		$1x10^{-3}$
	Pt-193m		$1x10^{-2}$
	Pt-197m		$1x10^{-2}$
	Pt-197		$1x10^{-3}$
Potassium (19)	K-42		$3x10^{-3}$
Praseodymium (59)	Pr-142		$3x10^{-4}$
	Pr-143		$5x10^{-4}$
Promethium (61)	Pm-147		$2x10^{-3}$
	Pm-149		$4x10^{-4}$
Rhenium (75)	Re-183		$6x10^{-3}$
	Re-186		$9x10^{-4}$
	Re-188		$6x10^{-4}$
Rhodium (45)	Rh-103m		$1x10^{-1}$
	Rh-105		$1x10^{-3}$
Rubidium (37)	Rb-86		$7x10^{-4}$
Ruthenium (44)	Ru-97		$4x10^{-3}$
	Ru-103		$8x10^{-4}$
	Ru-105		$1x10^{-3}$
	Ru-106		$1x10^{-4}$
Samarium (62)	Sm-153		$8x10^{-4}$
Scandium (21)	Sc-46		$4x10^{-4}$
	Sc-47		$9x10^{-4}$
	Sc-48		$3x10^{-4}$
Selenium (34)	Se-75		$3x10^{-3}$
Silicon (14)	Si-31		$9x10^{-3}$
Silver (47)	Ag-105		$1x10^{-3}$
	Ag-110m		$3x10^{-4}$
	Ag-111		$4x10^{-4}$
Sodium (11)	Na-24		$2x10^{-3}$
Strontium (38)	Sr-85		$1x10^{-3}$
	Sr-89		$1x10^{-4}$
	Sr-91		$7x10^{-4}$
	Sr-92		$7x10^{-4}$
Sulfur (16)	S-35	$9x10^{-8}$	$6x10^{-4}$
Tantalum (73)	Ta-182		$4x10^{-4}$
Technetium (43)	Tc-96m		$1x10^{-1}$
	Tc-96		$1x10^{-3}$
Tellurium (52)	Te-125m		$2x10^{-3}$
	Te-127m		$6x10^{-4}$

	Te-127		$3x10^{-3}$
	Te-129m		$3x10^{-4}$
	Te-131m		$6x10^{-4}$
	Te-132		$3x10^{-4}$
Terbium (65)	Tb-160		$4x10^{-4}$
Thallium (81)	Tl-200		$4x10^{-3}$
	Tl-201		$3x10^{-3}$
	Tl-202		$1x10^{-3}$
	Tl-204		$1x10^{-3}$
Thulium (69)	Tm-170		$5x10^{-4}$
	Tm-171		$5x10^{-3}$
Tin (50)	Sn-113		$9x10^{-4}$
	Sn-125		$2x10^{-4}$
Tungsten (Wolfram) (74)	W-181		$4x10^{-3}$
	W-187		$7x10^{-4}$
Vanadium (23)	V-48		$3x10^{-4}$
Xenon (54)	Xe-131m	$4x10^{-6}$	
	Xe-133	$3x10^{-6}$	
	Xe-135	$1x10^{-6}$	
Ytterbium (70)	Yb-175		$1x10^{-3}$
Yttrium (39)	Y-90		$2x10^{-4}$
	Y-91m		$3x10^{-2}$
	Y-91		$3x10^{-4}$
	Y-92		$6x10^{-4}$
	Y-93		$3x10^{-4}$
Zinc (30)	Zn-65		$1x10^{-3}$
	Zn-69m		$7x10^{-4}$
	Zn-69		$2x10^{-2}$
Zirconium (40)	Zr-95		$6x10^{-4}$
	Zr-97		$2x10^{-4}$
Beta and/or gamma emitting radioactive material not listed above with half-life of less than 3 years.		$1x10^{-10}$	$1x10^{-6}$

[1/]Values are given in Column I only for those materials normally used as gases.
[2/]ì Ci/g are for solids.

NOTE 1: Many radioisotopes transform into isotopes which are also radioactive. In expressing the concentrations in Schedule A, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of 410 IAC 5-3-4 where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Schedule A for the specific isotope when not in combination. The sum of such ratios may not exceed "1".

EXAMPLE:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} \leq 1$$

NOTE 3: To convert ì Ci/ml to SI units of megabecquerels per liter multiply the above values by 37.

EXAMPLE: Zirconium (40) Zr-97 ($2x10^{-4}$ ì Ci/ml multiplied by 37 is equivalent to $74x10^{-4}$ MB/q/l).

410 IAC 5-3-27 Schedule of exempt quantities

Sec. 27.

SCHEDULE B
EXEMPT QUANTITIES

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10

Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152) 9.2h	100
Europium-152 (Eu 152) 13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Flourine-18 *[sic., Fluorine]* (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-68 (Ge 68)	100
Germanium-71 (Ge 71)	100
Gold-195 (Au 195)	100
Gold-198 (Au 198)	100

Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100

Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 142)	100
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Radium-226 (Ra 226)	1
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100

Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m(Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1

NOTE 1: For purposes of 410 IAC 5-3-10(f)(1)(ii) where there is involved a combination of isotopes, the limit for the combination should be derived as follows:

Determine the amount of each isotope possessed and 1,000 times the amount in Schedule B for each of those isotopes when not in combination. The sum of the ratios of those quantities may not exceed 1.

EXAMPLE:

$$\frac{\text{Amt. of Isotope A possessed}}{\text{1000 x Schedule B quantity for Isotope A}} + \frac{\text{Amt. of Isotope B Possessed}}{\text{1000 x Schedule B quantity for Isotope B}} \leq 1$$

NOTE 2: To convert microcuries (ì Ci) to SI units of kilobecquerels (kBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (10ì Ci mulitiplied by 37 is equivalent to 370 kBq).

410 IAC 5-3-28 Schedule of medical use groups

Sec. 28. Schedule C

Group I. Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion (does not include uses involving imaging and tumor localizations)

(1) Chromium-51 as sodium chromate or labeled human serum albumin.

(2) Cobalt-57 as labeled cyanocobalamin.

(3) Cobalt-58 as labeled cyanocobalamin.

(4) Cobalt-60 as labeled cyanocobalamin.

(5) Iodine-123 as sodium iodide.
(6) Iodine-125 as sodium iodide, iodinated human serum albumin, oleic acid, or sodium iothalamate.
(7) Iodine-131 as sodium iodide, iodinated human serum albumin, labeled rose bengal, triolein, or sodium iodohippurate.
(8) Iron-59 as citrate.
(9) Potassium-42 as chloride.
(10) Sodium-24 as chloride.
(11) Technetium-99m as pertechnetate.
(12) Any radioactive material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution or excretion for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or a "New Drug Application" (NDA) has been accepted by the Food and Drug Administration (FDA).

Group II. Use of prepared radiopharmaceuticals for diagnostic studies involving imaging and tumor localizations

(1) Chromium-51 as human serum albumin.
(2) Fluorine-18 in solution.
(3) Gallium-67 as citrate.
(4) Gold-198 in colloidal form.
(5) Indium-113m as chloride.
(6) Iodine-123 as sodium iodide.
(7) Iodine-125 as sodium iodide or fibrinogen.
(8) Iodine-131 as sodium iodide, iodinated human serum albumin, macroaggregated iodinated human serum albumin, colloidal (microaggregated) iodinated human serum albumin, rose bengal, or sodium iodohippurate.
(9) Mercury-197 as chlormerodrin.
(10) Mercury-203 as chlormerodrin.
(11) Selenium-75 as selenomethionine.
(12) Strontium-85 as nitrate.
(13) Strontium-87m as chloride.
(14) Technetium-99m as pertechnetate, sulfur colloid, or macroaggregated human serum albumin.
(15) Thallium-201 as chloride.
(16) Ytterbium-169 as pentatate sodium.
(17) Any radioactive material in a radiopharmaceutical prepared from a reagent kit listed in (3) of Group III.
(18) Any radioactive material in a radiopharmaceutical and for a diagnostic use involving imaging except those in gaseous forms for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or a "New Drug Application" (NDA) has been accepted by the Food and Drug Administration (FDA).

Group III. Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing radioactive material for certain diagnostic uses

(1) Molybdenum-99/technetium-99m generators for the elution of technetium-99m as pertechnetate.
(2) Technetium-99m as pertechnetate for use with reagent kits for preparation and use of radiopharmaceuticals containing technetium-99m as provided in (3) and (6) of this group.
(3) Reagent kits for preparation of technetium-99m labeled:
(i) sulfur colloid;
(ii) pentatate sodium;
(iii) human serum albumin microspheres;
(iv) polyphosphates;
(v) macroaggregated human serum albumin;
(vi) etidronate sodium;
(vii) stannous pyrophosphate;
(viii) human serum albumin;
(ix) medronate sodium;
(x) gluceptate sodium; and
(xi) oxidronate sodium.
(4) Tin-113/indium-113m generators for the elution of indium-113m as chloride.
(5) Yttrium-87/strontium-87m generators for the elution of strontium-87m.
(6) Any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for which generator or reagent kit a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

Group IV. Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety

(1) Iodine-131 as iodide for treatment of hyperthyroidism and cardiac dysfunction.

(2) Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases.

(3) Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions.

(4) Any radioactive material in a radiopharmaceutical and for a therapeutic use not normally requiring hospitalization for purposes of radiation safety for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or a "New Drug Application" (NDA) has been accepted by the Food and Drug Administration (FDA).

Group V. Use of prepared radiopharmaceuticals for certain therapeutic uses that normally require hospitalization for purposes of radiation safety

(1) Gold-198 as colloid for intracavitary treatment of malignant effusions.

(2) Iodine-131 as iodide for treatment of thyroid carcinoma.

(3) Any radioactive material in a radiopharmaceutical and for a therapeutic use normally requiring hospitalization for radiation safety reasons for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or a "New Drug Application" (NDA) has been accepted by the Food and Drug Administration (FDA).

Group VI. Use of sources and devices containing radioactive material for certain medical uses

(1) Americium-241 as a sealed source in a device for bone mineral analysis.

(2) Cesium-137 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer.

(3) Cobalt-60 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer.

(4) Gold-198 as seeds for interstitial treatment of cancer.

(5) Iodine-125 as a sealed source in a device for bone mineral analysis.

(6) Iodine-125 as seeds for interstitial treatment of cancer.

(7) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer.

(8) Radon-222 as seeds for topical, interstitial, and intracavitary treatment of cancer.

(9) Radium-226 as a sealed source for topical, interstitial, and intracavitary treatment of cancer.

(10) Strontium-90 sealed in an applicator for treatment of superficial eye conditions.

410 IAC 5-3-29 Schedule of limits for broad licenses

Sec. 29.

SCHEDULE D
LIMITS FOR BROAD LICENSES

Radioactive	Col.I	Col.II
Material	curies	curies
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1.
Cerium-141	10	0.1
Cerium-143	10	0.1

Cerium-144	0.1	0.001
Cesium-131	100	1.
Cesium-134m	100	1.
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.
Chromium-51	100	1.
Cobalt-57	10	0.1
Cobalt-58m	100	1.
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2 h)	10	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1.
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1.
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1.
Indium-113m	100	1.
Indium-114m	1	0.01
Indium-115m	100	1.
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1.
Krypton-87	10	0.1

Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1.
Osmium-185	1	0.01
Osmium-191m	100	1.
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1.
Platinum-193	10	0.1
Platinum-197m	100	1.
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10.
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1.
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01

Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10.
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10.
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1.

Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above.	0.1	0.001

NOTE 1: to convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (Col. II) (0.01 Ci multiplied by 37 is equivalent to 0.37 GBq).

410 IAC 5-3-30 Certification of medical use under general license (form U)

Sec. 30. Board Form "U"

(Date)

CERTIFICATE-MEDICAL USE OF RADIOACTIVE MATERIAL UNDER GENERAL LICENSE

410 IAC 5-3-7(h) establishes a general license authorizing physicians to possess certain small quantities of I-125, I-131, Co-57, Co-58, Co-60, and Cr-51 for specified diagnostic uses. Possession of radioactive material under 410 IAC 5-3-7(h) is not authorized until the physician has filed board form U and received from the board a validated copy of board form U with certification number assigned.

INSTRUCTIONS

Submit this form in triplicate to the Radiological Health Section, Indiana State Board of Health. A certification number will be assigned and a validated copy of board form U will be returned. Please print or type your name and address (including ZIP Code), within the lines below:

Certification Number:
(Leave this space blank-number to be assigned by the board)

I am a duly licensed physician [authorized to dispense drugs] in the practice of medicine. My Indiana license number is: _____.

CERTIFICATE

I hereby certify that:

1. All information in this certificate is true and complete.
2. I have appropriate radiation measuring instruments to carry out the diagnostic procedures for which I will use radioactive material under the general license of 410 IAC 5-3-7(h) and I am competent in the use of such instruments.
3. I understand that board rules require that any change in the information furnished on this certificate be reported to the board within 30 days from the date of such change.
4. I have read and understand the provisions of 410 IAC 5-3-7(h) of the Indiana Rule for Radiation Control [410 IAC 5]; and I understand that I am required to comply with those provisions as to all radioactive material which I receive, possess, use, or transfer under the general license for which this certificate is filed with the board:

Date: _____ By: _____

(Signature of person filing form)

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 410 IAC 5-3-7(h)

Medical Diagnostic Uses

(1) A general license is hereby issued to any physician to receive, possess, transfer, or use radioactive material set forth below for the stated diagnostic uses, provided, however, that the use is in accordance with the provisions of 410 IAC 5-3-7(h)(2), (3), and (4), the radioactive material is in the form of capsules, disposable syringes, or other prepackaged individual doses; and the radioactive material has been manufactured in accordance with the specific license issued by the board pursuant to 410 IAC 5-3-13(g) or by the U.S. Nuclear Regulatory Commission, any agreement state, or a licensing state pursuant to equivalent regulations authorizing distribution to persons generally licensed pursuant to 410 IAC 5-3-7(h) or its equivalent:

(i) chromium-51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time;

(ii) cobalt-57 for the measurement of intestinal absorption of cyanocobalamin;

(iii) cobalt-58 for the measurement of intestinal absorption of cyanocobalamin;

(iv) cobalt-60 for the measurement of intestinal absorption of cyanocobalamin;

(v) iodine-125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(vi) iodine-131 as sodium iodide for measurement of thyroid uptake; and

(vii) iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume.

(2) No physician shall receive, possess, use or transfer radioactive material pursuant to the general license established by 410 IAC 5-3-7(h)(1) until he has filed board form "U," "Certificate Medical Use of Radioactive Material Under General License" with the board and received from the board a validated copy of the board form "U" with certification number assigned. The generally licensed physician shall furnish on board form "U" the following information and such other information as may be required by that form:

(i) name and address of the generally licensed physician;

(ii) a statement that the generally licensed physician is a duly licensed physician [authorized to dispense drugs] in the practice of medicine in this state; and

(iii) a statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use radioactive material under the general license of 410 IAC 5-3-7(h) and that he is competent in the use of such instruments.

(3) A physician who receives, possesses or uses a pharmaceutical containing radioactive material pursuant to the general license established by 410 IAC 5-3-7(h)(1) shall comply with the following:

(i) he shall not possess at any one time, pursuant to the general license in 410 IAC 5-3-7(h)(1) more than

(A) 200 microcuries of iodine-131,

(B) 200 microcuries of iodine-125,

(C) 5 microcuries of cobalt-57,

(D) 5 microcuries of cobalt-58,

(E) 5 microcuries of cobalt-60, and

(F) 200 microcuries of chromium-51;

(ii) he shall store the pharmaceutical until administered in the original shipping container, or a container providing equivalent radiation protection;

(iii) he shall use the pharmaceutical only for the uses authorized by 410 IAC 5-3-7(h)(1);

(iv) he shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age; and

(v) he shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the board, the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

(4) The generally licensed physician possessing or using radioactive material under the general license of 410 IAC 5-3-7(h)(1) shall report in duplicate to the board, any changes in the information furnished by him in the "Certificate Medical Use of Radioactive Material Under General License," board form "U." The report shall be submitted within 30 days after the effective date of such change.

(5) Any person using radioactive material pursuant to the general license of 410 IAC 5-3-7(h)(1) is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to the radioactive material covered by the general license.

NOTE: 410 IAC 5-3-13(g) requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to include one of the following statements in the label affixed to the container or in the leaflet or brochure which accompanies the radiopharmaceutical:

This radioactive drug may be received, possessed, and used only by physicians licensed [to dispense drugs] in the practice of medicine. Its receipt, possession, use, and transfer are subject to the regulations and a general license or its equivalent of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

_____

(Name of Manufacturer)

This radioactive drug may be received, possessed, and used only by physicians licensed [to dispense drugs] in the practice of

medicine. Its receipt, possession, use, and transfer are subject to the rules and a general license or its equivalent of a licensing state.

_____

(Name of Manufacturer)

NOTE

If larger quantities or other forms of radioactive material than those specified in the general license of 410 IAC 5-3-7(h) are required, the physician should file an "Application for Radioactive Material License," and obtain a specific radioactive material license. Copies of application and certification forms may be obtained from the Radiological Health Section, Indiana State Board of Health.

410 IAC 5-3-31 Certification of in vitro testing under general license (form V)

Sec. 31. Board Form "V"

(Date)

CERTIFICATE *IN VITRO* TESTING WITH
RADIOACTIVE MATERIAL UNDER
GENERAL LICENSE

410 IAC 5-3-7(i)(1) establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to possess certain small quantities of radioactive material for *in vitro* clinical or laboratory tests not involving the internal or external administration of the radioactive material or the radiation therefrom to human beings or animals. Possession of radioactive material under 410 IAC 5-3-7(i) is not authorized until the physician, veterinarian, clinical laboratory, or hospital has filed board form V and received from the board a validated copy of board form V with certification number.

INSTRUCTIONS

Submit this form in triplicate to the Radiological Health Section, Indiana State Board of Health. A certification number will be assigned and a validated copy of board form V will be returned.

_____

1. Please print or type within the lines, below, the name and address (including ZIP Code) of the physician, veterinarian, clinical laboratory, or hospital for whom or for which this form is filed.

3

2. I hereby apply for a certification pursuant to 410 IAC 5-3-7(i) for use of radioactive material for (Please check one):

a. Myself, a duly licensed physician [authorized to dispense drugs] in the practice of medicine.

b. The above-named clinical laboratory.

c. The above-named hospital.

d. Myself, a duly licensed veterinarian.

3. To be completed by the board.

Certification number:

(Leave this space blank number to be assigned by the board)

4. If place of use is different from address in item 1, please give complete address:

_____

5. Certification:

I hereby certify that:

a. All information in this certification is true and complete.

b. Appropriate radiation measuring instruments are available to carry out the tests for which radioactive material will be used under the general license of 410 IAC 5-3-7(i). The tests will be performed only by personnel competent in the use of the instruments and in the handling of the radioactive material.

c. I understand that board rules require that any change in the information furnished on this certificate be reported to the board, within 30 days from the effective date of such change.

d. I have read and understand the provisions of 410 IAC 5-3-7(i); and I understand that compliance with those provisions is required as to all radioactive material which is received, acquired, possessed, used, or transferred under the general license for which this certificate is filed with the board.

Date: _____ By: _____

(Signature of person filing form)

_____

(Printed name and title of position of person filing form)

CONDITIONS AND LIMITATIONS OF GENERAL
LICENSE 410 IAC 5-3-7(i)

General License for Use of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing

(1) A general license is hereby issued to any physician, veterinarian, clinical laboratory, or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 410 IAC 5-3-7(i)(2), (3), (4), (5), and (6), the following radioactive materials in prepackaged units for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(i) Carbon-14, in units not exceeding 10 microcuries each.

(ii) Cobalt-57, in units not exceeding 10 microcuries each.

(iii) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each.

(iv) Iodine-125, in units not exceeding 10 microcuries each.

(v) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.

(vi) Iodine-131, in units not exceeding 10 microcuries each.

(vii) Iron-59, in units not exceeding 20 microcuries each.

(viii) Selenium-75, in units not exceeding 10 microcuries each.

(2) No person shall receive, acquire, possess, use, or transfer radioactive material pursuant to the general license established by 410 IAC 5-3-7(i)(1) until he has filed board form "V," "Certificate *In Vitro* Testing with Radioactive Material Under General License," with the board and received from the board a validated copy of board form "V" with certification number assigned, or until he has been authorized pursuant to 410 IAC 5-3-11(c)(3) to use radioactive material under the general license in 410 IAC 5-3-7(i). The physician, veterinarian, clinical laboratory, or hospital shall furnish on board form "V" the following information and such other information as may be required by that form:

(i) name and address of the physician, veterinarian, clinical laboratory, or hospital;

(ii) the location of use; and

(iii) a statement that the physician, veterinarian, clinical laboratory, or hospital has appropriate radiation measuring instruments to carry out *in vitro* clinical or laboratory tests with radioactive material as authorized under the general license in 410 IAC 5-3-7(i)(1) and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses, or uses radioactive material pursuant to the general license established by 410 IAC 5-3-7(i)(1) shall comply with the following:

(i) The general licensee shall not possess at any one time, pursuant to the general license in 410 IAC 5-3-7(i)(1), at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-175, iron-59, and/or cobalt-57 in excess of 200 microcuries.

(ii) The general licensee shall store the radioactive material until used, in the original shipping container or in a container providing equivalent radiation protection.

(iii) The general licensee shall use the radioactive material only for the uses authorized by 410 IAC 5-3-7(i)(1).

(iv) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the board, the U.S. Nuclear Regulatory Commission, any agreement state, or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(v) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in 410 IAC 5-3-7(i)(1)(viii) as required by 410 IAC 5-4-16.

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 410 IAC 5-3-7(i)(1):

(i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 410 IAC 5-3-13(h) or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any agreement state or licensing state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under 410 IAC 5-3-7(i) or its equivalent, and

(ii) Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on the label affixed to each prepackaged unit or

appears in a leaflet or brochure which accompanies the package:

(A) This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the rules and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

_____

Name of Manufacturer

(B) This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a licensing state.

_____

Name of Manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 410 IAC 5-3-7(i)(1) shall report in writing to the board, any changes in the information furnished by him in the "Certificate *In Vitro* Testing with Radioactive Material Under General License," board form "V." The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of 410 IAC 5-3-7(i)(1) is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 410 IAC 5-3-7(i)(1)(viii) shall comply with the provisions of 410 IAC 5-4-16, 410 IAC 5-4-22, and 410 IAC 5-4-23.

NOTE

If larger quantities or other forms of radioactive material than those specified in the general license of 410 IAC 5-3-7(i) are required, an "Application for Radioactive Material License," should be filed to obtain a specific radioactive material license. Copies of application and certification forms may be obtained from the Radiological Health Section, Indiana State Board of Health.

410 IAC 5-3-32 Certification of use of depleted uranium under general license (form W)

Sec. 32. Board Form "W"

(Date)

REGISTRATION CERTIFICATE USE OF DEPLETED URANIUM UNDER GENERAL LICENSE

410 IAC 5-3-6(d) establishes a general license authorizing the use of depleted uranium contained in industrial products or devices for mass-volume applications. This form W shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium.

INSTRUCTIONS

1. Submit this form in triplicate to:
   Radiological Health Section
   Indiana State Board of Health
   1330 West Michigan Street
   Indianapolis, IN 46206
2. Please print or type the name and address (including ZIP Code) of the registrant for whom this form is filed. Position the first letter of the address below the left dot and do not extend the address beyond the right dot. (A file number will be assigned and a copy of form W will be returned.)
3. I hereby file form W pursuant to 410 IAC 5-3-6(d), for use of depleted uranium contained in industrial products or devices for mass-volume applications.
4. To be completed by the board.

FILE NUMBER: (Leave this space blank number to be assigned by board.)

5. Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in 410 IAC 5-3-6(d).

_____

6. Certification:

I hereby certify that:

a. All information in this registration certificate is true and complete.

b. The registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 410 IAC 5-3-6(d) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium.

c. I understand that board rules require that any changes in information furnished by a registrant on this registration certificate be reported in writing to the board within 30 days after the effective date of such change.

d. I understand that the registrant is required to comply with the provisions of 410 IAC 5-3-6(d) (reprinted as part of this form) with respect to all depleted uranium which he receives, acquires, uses, or transfers under the general license for which this registration certificate is filed with the board.

Date:_____ By: _____

(Signature of person filing form)

_____

(Printed name and title of person filing form)

Depleted Uranium in Industrial Products and Devices

(1) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 410 IAC 5-3-6(d)(2), (3), (4), and (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in 410 IAC 5-3-6(d)(1) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 410 IAC 5-3-13(m) or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an agreement state.

(3)(i) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1) shall file board form W "Registration Certificate Use of Depleted Uranium Under General License," with the board. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on board form W the following information and such other information as may be required by that form:

(A) Name and address of the registrant;

(B) A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 410 IAC 5-3-6(d)(1) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(C) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in 410 IAC 5-3-6(d)(3)(i)(B).

(ii) The registrant possessing or using depleted uranium under the general license established by 410 IAC 5-3-6(d)(1) shall report in writing to the board any changes in information furnished by him in board form W "Registration Certificate Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses or uses depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1):

(i) Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium.

(ii) Shall not abandon such depleted uranium.

(iii) Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 410 IAC 5-3-22. In the case where the transferee receives the depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1), the transferor shall furnish the transferee a copy of 410 IAC 5 and a copy of board form W. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or agreement state's regulation equivalent to 410 IAC 5-3-6(d)(1), the transferor shall furnish the transferee a copy of 410 IAC 5 and a copy of board form W accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or agreement state under requirements substantially the same as those in 410 IAC 5.

(iv) Within 30 days of any transfer, shall report in writing to the board the name and address of the person receiving the depleted uranium pursuant to such transfer.

(v) Shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1) is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to the depleted uranium covered by that general license.